MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT MAY 9, 2022

CON REVIEW NUMBER: FSF-FE-0322-005 SINGING RIVER HEALTH SYSTEM – OCEAN SPRINGS IMAGING CENTER ACQUISITION AND IMPLEMENTATION OF FIXED POSITRON EMISSION TOMOGRAPHY (PET) EQUIPMENT AND SERVICES AT OUTPATIENT IMAGING CENTER CAPITAL EXPENDITURE: \$2,655,120.00 LOCATION: OCEAN SPRINGS, JACKSON COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Singing River Health System ("SRHS" or the "Applicant") is a community owned, not-for-profit health system comprised of three (3) hospitals: Singing River Hospital - Pascagoula, Ocean Springs Hospital, and Singing River Gulfport Hospital. SRHS is located at 3109 Bienville Boulevard, Ocean Springs, Jackson County, Mississippi 39564. SRHS is governed by six (6) Board of Supervisors and six (6) Board of Trustees.

B. <u>Project Description</u>

Singing River Health System requests Certificate of Need ("CON") authority to purchase a fixed PET scanner and to provide PET services at its Ocean Springs Imaging Center ("Imaging Center"), a freestanding facility located at 3535 Bienville Boulevard, Ocean Springs, MS 39564. The Applicant states, on September 27, 2001, SRHS was previously awarded CON authority to provide mobile PET services at Ocean Springs Hospital and Singing River Hospital. SRHS states the mobile PET equipment is provided by Alliance HealthCare Services ("Alliance"). The Applicant asserts, if approved, SRHS will cease mobile PET services at each of its approved hospital locations and direct all PET scans to the fixed unit at the Imaging Center. The Applicant further states completion of the project is necessary to serve the Applicant's Cancer Center which relies heavily on PET services as part of its diagnosis and treatment of patients.

The Applicant states in July 2020, due to COVID -19, SRHS received an emergency waiver from the Mississippi State Department of Health ("MSDH" or the "Department") to temporarily implement a fixed PET scanner and services at the Imaging Center. SRHS asserts in January 2021, the Imaging Center was renovated to implement the emergency waiver granted by the Department. The Applicant states the renovation cost approximately \$325,620.00. The Applicant's application includes a lease agreement between the Applicant and GE, dated as of February 2021, for the lease of the fixed PET scanner. The initial term of the agreement is sixty (60) months; however, the fixed PET equipment may be purchased at month

twenty-four (24) and the buy-out cost is \$1,542,295.00. The lease cost for twenty-four (24) months is \$697,191.84. The Applicant asserts both the lease cost and the buy-out cost are included as part of the capital expenditure amount for fixed equipment and rounded up for a total cost of \$2,239,500.00.

The Applicant states the proposed project would continue the current lease payments until month twenty-four (24) which is January 2023. The Applicant would then purchase the current leased fixed PET equipment and continue to provide the previously approved temporary fixed PET services, past the current termination date of May 20, 2022. According to the Applicant, an interruption in services is not expected to occur as a result of the proposed project, as the Applicant can continue to offer mobile PET services at its hospital locations, should final approval of the proposed project occur after May 20, 2022.

SRHS affirms PET services at the Imaging Center will be available Monday through Thursday, on a normal eight (8) hour schedule, with flexibility to operate on Fridays as well. The Applicant states SRHS has historically provided and will continue to provide all supplies for the operation of its business. The Applicant asserts the only changes in operational expenses from the provision of mobile PET services will be those changes that result from the continued increase in scan volumes projected by the Applicant and the increase of 0.5 FTE to operate the unit, which has been implemented as part of operations under the emergency waiver.

The Applicant anticipates obligation of the capital expenditure as soon as possible after receiving the Department's approval. The Applicant asserts portions of the capital expenditure were already expended as part of implementing the emergency waiver, such as the renovation of the Imaging Center and payment of the first thirteen (13) monthly lease payments for the equipment. SRHS also states after receiving the Department's approval, service would begin as soon as possible.

The application contains a letter dated July 14, 2020, documenting site approval for the proposed project from the MSDH Division of Health Facilities Licensure and Certification.

SRHS states, through the proposed project, the Applicant intends to provide better quality and more efficient PET services to the patients of its Cancer Center and the residents of Jackson County and the surrounding service area. The Applicant states this proposed project will further the State Health Plan's goals of cost containment, as the equipment will be located in an existing facility (the Imaging Center). In addition, the Applicant states the monthly lease payments being made to Alliance since 2001 for use of its mobile PET equipment will also be eliminated. SRHS affirms the proposed equipment is more current and provides better technology than the current leased equipment from Alliance. The Applicant further states the proposed equipment will also be more efficient for patients, reducing wait times and scan times and increasing patient satisfaction. SRHS states the proposed project

will also yield higher quality scans. The Applicant states the granting of the proposed project will, therefore, also further the State Health Plan's goals of increasing the quality and accessibility of services.

The Applicant states no new construction took place to implement its emergency waiver for fixed PET equipment and services. The Applicant instead renovated existing space in its Imaging Center; thus, there was no site work, grounds work, drainage, parking or fencing work needed as part of the renovation. The Applicant affirms the existing mechanical and electrical systems were modified to support the fixed PET equipment. The Applicant further states the renovated area within the Imaging Center consisted of approximately 1,503 square feet.

The Applicant's application included a list of capital expenditure projects completed within the past two (2) years in excess of \$200,000. Those projects include the following:

- On May 26, 2020, the Applicant completed a renovation of the surgery waiting area within Ocean Springs Hospital.
- On December 20, 2020, the Applicant completed a renovation of its Cath Lab 1 at Ocean Springs Hospital. On July 12, 2021, the Applicant also completed a renovation of its Cath Lab 2 at Ocean Springs Hospital. The Applicant states the projects modified the spaces by improving the HVAC and electrical systems and by replacing existing Cath lab imaging equipment which had become outdated.
- In August 2021, the Applicant replaced a twenty (20) year old Magnetic Resonance Imaging (MRI) unit and updated the shielding and power supply to the replacement unit located at Singing River Gulfport.

The Applicant confirms complying with all applicable state statutes and regulations for the protection of the environment, including approved water supplies, sewage and water disposal, hazardous waste disposal, water pollution control, air pollution control, and radiation control.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Sections 41-7-173, 41-7-191(1)(d)(xv), and 41-7-193 of the Mississippi Code of 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health. MSDH will also review applications for a CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual, September 1, 2019, Revision*; all adopted rules, procedures, plans, criteria, and standards of the MSDH; and the specific criteria and standards listed below. The Department reviews projects for the provision of PET services if the proposed provider has not provided such service on a regular basis within the period of twelve (12) months prior to the time such service would be offered, regardless of the capital expenditure.

In accordance with Section 41-7-197(2) of the Mississippi Code of 1972, Annotated, as amended, any affected person may request a public hearing on this project within ten (10) days of publication of the staff analysis. The opportunity to request a hearing expires on May 19, 2022.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. <u>State Health Plan (SHP)</u>

The FY 2022 Mississippi State Health Plan, Second Edition contains policy statements, criteria and standards which the applicant is required to meet before receiving CON authority for the acquisition and implementation of fixed PET equipment and services. This application is in substantial compliance with the applicable policy, criteria and standards stated in the *Plan* for the acquisition of fixed PET equipment and the offering of PET services.

Policy Statements Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment including Cardiac only PET Scanner

Policy Statement 1 – CON Review Requirements: The Applicant states SRHS seeks this CON as the capital expenditure for the PET scanner and related equipment exceeds \$1,500,000.

Policy Statement 2 – Indigent/Charity Care: The Applicant affirms SRHS shall provide a reasonable amount of indigent/charity care as required by the *FY 2022 MS State Health Plan*.

Policy Statement 3 – Service Areas: The Applicant acknowledges that the State as a whole shall serve as a single service area in determining the need for a PET scanner.

Policy Statement 4 – Equipment to Population Ratio: SRHS submits, according to Policy Statement 15, the "Equipment to Population Ratio" requirement of Policy Statement 4 does not apply because SRHS' Cancer Center has been accredited by the Commission on Cancer, a program of the American College of Surgeons. The Applicant's application includes a three (3) year certificate of accreditation from the Commission on Cancer.

Policy Statement 5 – Access to Supplies: The Applicant states SRHS will have direct access to appropriate radiopharmaceuticals.

Policy Statement 6 – Services and Medical Specialties Required: SRHS affirms the PET scanner will function as a component of a comprehensive outpatient diagnostic service and will have the following modalities and capabilities on-site or through contractual arrangements:

- Computed Tomography (whole body)
- Magnetic Resonance Imaging (brain and whole body)
- Nuclear Medicine (cardiac, SPECT)
- Conventional Radiography
- The following medical specialties during operations hours:
 - Cardiology
 - Neurology
 - Neurosurgery
 - Oncology
 - Psychiatry
 - Radiology

Policy Statement 7 – Hours of Operation: The Applicant states the Imaging Center will have adequate scheduled hours to avoid an excessive backlog of cases. The Applicant's hours of operation for PET services are Monday through Thursday, 8:00 am to 5:00 pm, with flexibility to provide services on Fridays as needed for patient overflow.

Policy Statement 8 – CON Approval Preference: Not applicable.

Policy Statement 9 – CON Requirements: The Applicant acknowledges the criteria and standards contained in the State Health Plan pertain to both fixed and/or mobile PET scanner equipment.

Policy Statement 10 – CON Exemption: Not applicable.

Policy Statement 11 - Addition to a Health Care Facility: Not applicable.

Policy Statement 12 – Equipment Registration: SRHS affirms the Applicant will provide the Department with the registration/serial number of the CON-approved PET scanner.

Policy Statement 13 - Certification: Not applicable.

Policy Statement 14 – Conversion from Mobile to Fixed Service: SRHS states the Applicant acknowledges that the conversion from a mobile PET service to a fixed PET service site will not be considered the establishment of a new service and will not require CON review under Section 513.02.13; provided, however, that the facility submit an application for a determination of non-reviewability prior to converting the service.

Policy Statement 15 – Applicants with an Accredited Cancer Center: SRHS affirms the Applicant has a cancer center accredited by the Commission on Cancer, a program of the American College of Surgeons.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment including Cardiac only PET Scanner

Need Criterion 1: Minimum Procedures/Population

a. The Applicant states, as a methodology for projecting the need for the fixed PET unit, the Applicant relies on its historical utilization for PET services together with the commitments of providers to refer procedures to the fixed PET unit. The Applicant notes, upon approval and implementation of the proposed project, the Applicant will cease mobile PET services at its two (2) approved hospital locations and all patient volume will shift to the fixed PET unit at its Imaging Center.

For Fiscal Year 2016, the Applicant states 345 PET scans were performed at Ocean Springs Hospital and 376 PET scans were performed at Singing River Hospital for a total of 721 scans by SRHS. The Applicant notes that each location had access to a mobile PET scanner once per week during this time span. The Applicant states in FY 2020, as reported in the *FY 2022 State Health Plan*, the Applicant performed 767 PET scans at Ocean Springs Hospital and 433 scans at Singing River Hospital, for an annual total 1,200 PET scans.

The Applicant states, in addition to the volume of mobile PET services documented in the State Health Plan, SRHS obtained affidavits from referring providers. According to the Applicant, these providers, based on their historical referral patterns, projected the number of patients they expect to refer. The Applicant submits the total number of PET scans projected in Year 1 of the proposed project through the affidavits is 1,408. The Applicant notes this figure does not represent all providers who referred patients for PET scans in previous years. The Applicant further states based on these facts, the total number of scans the applicant projects it will perform in Years 1, 2, and 3 are 1,440, 1,483, and 1,528 scans respectively.

b. SRHS submits, per Need Criterion 8 (Applicants with an Accredited Cancer Center), applicants seeking to acquire and operate a fixed PET scanner as part of a Cancer Center accredited by the Commission on Cancer, a program of the American College of Surgeons, shall be exempt from the requirements set forth in Need

Criterion 1b (Minimum Procedures/Populations). The Applicant states, because its Cancer Center is accredited by the Commission on Cancer, it is not required to meet Need Criterion 1b.

Need Criterion 2: Business Registration

The Applicant affirms SRHS is a community owned, not-for-profit health system authorized by statute to do business in Mississippi.

Need Criterion 3: Approval of Additional PET Equipment

states per Need Criterion 8 (Applicants with an Accredited SRHS Cancer Center) applicants seeking to acquire and operate а fixed PET scanner as part of а cancer center accredited bv the Commission the American College on Cancer, а program of of Surgeons, shall be exempt from the requirement set forth in Need Criterion 3. SRHS further states because the Applicant's Cancer Center is accredited by the Commission on Cancer, it is not required to meet Need Criterion 3.

Need Criterion 4: Division of Radiological Health Approval

The Applicant affirms SRHS will receive approval from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

Need Criterion 5: Data Requirements

The Applicant affirms the data listed in Need Criterion 5 will be kept and made available to MSDH upon request.

Need Criterion 6: Fixed/Minimum Value Contracts

SRHS affirms the Applicant will not contract the equipment to be rented, leased, or otherwise used by another qualified provider on a contractual basis.

Need Criterion 7: CON Approval/Exemption for PET Equipment

The Applicant submits currently SRHS has temporary approval from the Department to operate a fixed PET scanner at its Imaging Center as part of the emergency waiver issued by the State Health Officer. The Applicant asserts the approval expires May 20, 2022. The Applicant states, if the approval expires before SRHS receives final approval of the CON Application, SRHS will cease to utilize the fixed equipment until final approval is obtained.

Need Criterion 8: Applicants with an Accredited Cancer Center

The Applicant asserts, because the Applicant's Cancer Center is accredited by the Commission on Cancer, it is not required to meet Need Criterion 1b and 3.

The Applicant's application includes a three (3) year certificate of accreditation from the Commission on Cancer.

Certificate of Need Criteria and standards for Offering of Fixed or Mobile Positron Emission Tomography (PET) Services including Cardiac only PET Scanner

Need Criterion 1: Minimum Procedures

SRHS states the Applicant relies on its historical utilization for PET services together with projections of referring providers to exceed the minimum number of procedures required per year. For FY 2016, the Applicant asserts 345 PET scans performed its Ocean Springs Hospital 376 PET were at and scans were performed at its Singing River Hospital for a total of 721 scans performed by SRHS. The Applicant notes each location had access to a mobile PET scanner once per week during this time span.

In FY 2020, the Applicant performed 767 PET scans at Ocean Springs Hospital and 433 scans at Singing River Hospital for an annual total of 1,200 PET scans. The Applicant states, upon implementation of the proposed project, SRHS will cease offering mobile PET services at each hospital location and will direct all PET scans to the fixed unit at its Imaging Center.

In addition to the volume of mobile PET services documented in the State Health Plan, the Applicant obtained affidavits from referring providers who, based on their historical referral patterns, projected the number of patients they expect to refer. The Applicant asserts the 1,408 PET scans projected in Year 1 is based solely on affidavits. The Applicant submits this figure does not represent all providers who have referred patients for PET scans in previous years. The Applicant further states, based on these facts, the total number of scans the Applicant projects to perform in Years 1, 2, and 3 are 1,440,1,483, and 1,528 respectively.

Need Criterion 2: PET Equipment Utilized by Multiple Providers

The Applicant affirms this need criterion is not applicable.

Need Criterion 3: Quality Control and Environmental Requirements

The Applicants affirms it will provide fixed PET services in a physical environment that conforms to federal standards, manufacturer's specifications, licensing

agencies' requirements, and which address the areas identified in Need Criterion 3.

Need Criterion 4: Division of Radiological Health Approval

The Applicant affirms that it will receive approval from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

Need Criterion 5: Provision of On-Site Medical Cyclotron

SRHS states the Applicant has access to a supply of cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and a radiopharmaceutical production facility within a two-hour air transport radius.

Need Criterion 6: Staffing Requirements

- a. The Applicant affirms one (1) or two (2) radiologists will be housed in the Imaging Center along with the PET scanner at all times. The Applicant states both radiologists have been licensed by the State on the Applicant's radioactive material ("RAM") license as authorized users and can supervise the use of radionuclides by the technologists. The Applicant submits each radiologist has had primary responsibility for at least a one-year period prior to submission of the CON application in the acquisition and interpretation of tomographic images. The Applicant further states each has received specialty board certification in Diagnostic Radiology from the American Board of Radiology.
- b. The Applicant states this criterion is not applicable.
- c. SRHS states the Applicant has a service contract with General Electric to provide engineers for maintenance, and a service contract with West Physics to provide physics personnel when needed during PET service hours. The Applicant's application included the service contracts. The Applicant further states all contracted personnel have training and experience in the operation and maintenance of the PET equipment.
- d. SRHS states the Applicant has an employed radiation safety officer available at all times with postgraduate specialty training in radiation safety. The Applicant further states there is no cyclotron operated on-site.
- e. SRHS states the Applicant has an experienced certified nuclear technologist with expertise in computed tomographic nuclear medicine imaging procedures, who has performed procedures on

the fixed PET scanner since it was initiated in February 2021. SRHS states the individual will continue in his current role and operate at the expected volume levels, which are consistent with those experienced in 2021.

f. The Applicant affirms all appropriate support personnel are available as needed during PET services hours.

Need Criterion 7: Management of Medical Emergencies

SRHS states the Applicant will rely on emergency services through 911 dispatch to respond to medical emergencies within the PET unit.

Need Criterion 8: Accommodating Referred Patients

The Applicant affirms it will comply with this need criterion.

Need Criterion 9: Medical Necessity

The Applicant affirms it will comply with this need criterion.

Need Criterion 10: Notification of Procedures Offered

SRHS affirms the Applicant will maintain a current listing of PET procedures for use by referring physicians.

Need Criterion 11: Data Requirements

SRHS affirms the Applicant will maintain the data identified in Need Criterion 11 and will make it available to MSDH upon request.

Need Criterion 12: CON Approval/Exemption for PET Equipment

The Applicant affirms it will obtain CON approval or exemption for its PET equipment by MSDH before offering the service.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, September 1, 2019, Revision* addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with the general review criteria contained in the manual.

GR Criterion 1- State Health Plan

The Applicant asserts the proposed project is in full compliance with the criteria and standards for the acquisition of fixed PET equipment and implementation of fixed PET services contained in the *FY 2022 Mississippi State Health Plan, Second Edition.*

GR Criterion 2 – Long Range Plan

SRHS submits part of its long-range plan is to grow its Cancer Center by bringing in more oncologists and expanding accessibility for its services. The Applicant states, over the last number of years, SRHS has increased the number of oncologists and bolstered the volume of services offered by its Cancer Center. The Applicant asserts the performance of PET scans is critical to the diagnosis and treatment of cancer patients.

Additionally, the Applicant asserts it has sought to eliminate the ongoing PET equipment lease expense it has maintained since approximately 2001. The Applicant states fixed PET equipment has a higher quality of images than mobile PET equipment and is operated at speeds faster than the mobile equipment; therefore, the proposed project satisfies the goal of increasing the quality and efficiency of the services it offers. The Applicant further states after evaluating how best to accomplish these goals, SHRS determined that the proposed project was the best choice.

GR Criterion 3 – Availability of Alternatives

- **a.** Advantages and Disadvantages: The Applicant states SRHS considered all available alternatives to the proposed project. Specifically, the Applicant considered the following alternatives:
 - 1. Continuing to lease mobile PET equipment one (1) day per week at each hospital location;
 - 2. Continuing to lease mobile PET equipment and expanding the number of days available for mobile PET scans;
 - 3. Building a freestanding facility and buying fixed PET equipment; or
 - 4. Renovating existing space within its Imaging Center and purchasing fixed PET equipment.

The Applicant states the proposed project best serves its intended purposes.

b. New Construction Projects: The Applicant affirms no new construction for

the proposed project.

c. Beneficial Effects to the Health Care System: The Applicant affirms fixed PET equipment provides higher quality scans, which is of great importance to all physicians, especially those serving patients within the Applicant's Cancer Center who rely on PET scans for diagnosis and treatment of patients. The Applicant states the fixed equipment also provides more efficient services than the mobile equipment currently being leased. The Applicant submits using fixed PET equipment increases accessibility to PET scans because the Applicant is able to schedule patients throughout the week and is not beholden to scheduling limitations of providers of mobile PET equipment.

SRHS states purchasing fixed PET equipment eliminates the ongoing lease costs associated with using a mobile PET unit owned by a third-party. The Applicant asserts the proposed project will benefit the health care system of Ocean Springs and Pascagoula, Jackson County, and the surrounding areas. The Applicant further states the proposed project promotes cost effectiveness as it calls for the renovation of existing space within the Applicant's existing Imaging Center rather than constructing a new facility.

- **d. Effective and Less Costly Alternatives:** SRHS states there is no less costly alternative for the proposed project.
 - i. Unnecessary Duplication of Services: The Applicant states this project will not create an unnecessary duplication of services because the unit will principally serve the oncology patients receiving treatment at the Applicant's Cancer Center and patients referred by affiliated providers.
 - ii. Efficient Solution: The Applicant asserts patients who received services from the fixed PET unit, approved as part of the emergency waiver, are overwhelmingly patients referred by providers affiliated with its Cancer Center.
- e. Improvements and Innovations: SRHS submits the proposed project promotes cost effectiveness as the work to implement the fixed PET unit and services already occurred in order to effectuate the emergency waiver that the Applicant currently operates under.
- f. Relevancy. SRHS submits the proposed project will facilitate community health needs by reducing cancer mortality and improving treatment outcomes through early detection of cancer and by improving clinical information through higher quality imaging for use by treating physicians to

ensure effective treatment. The Applicant states its desire to have a fixed PET unit is to provide necessary services to its Cancer Center patients, who require timely access to services as oncologists rely on PET scans for the diagnosis and treatment of patients. The Applicant asserts to continue to utilize mobile PET services would limit the capabilities of its Cancer Center patients to receive needed scans as quickly as possible.

GR Criterion 4 - Economic Viability

- a. **Proposed Charge:** The Applicant affirms the proposed charges for services are the same as the charges currently imposed on patients receiving services under the authority of the emergency waiver.
- b. Projected Levels of Utilization: The Applicant states it relies on its own historical utilization for PET services together with the projections of providers who refer procedures to the fixed PET unit as a means to identify the need level for its service area. The Applicant affirms in addition to the volume of mobile PET services documented in the FY 2022 Mississippi State Health Plan, Second Edition, the Applicant obtained affidavits from referring providers who, based on their historical referral patterns, projected the number of patients they expect to refer in Year 1 of the proposed project. The Applicant states the affidavits alone projected a total number of PET scans of 1,408. The Applicant further states the projected utilization of 1,440, 1,483, and 1,528 in Years 1 through 3 respectively is consistent with the Applicant's actual experience in its service area.
- **c. Financial Feasibility Study:** The application included a financial feasibility study prepared by the facility's Chief Financial Officer.
- d. Financial Forecasts: The Applicant states any deviations from the historical financials are due entirely to the increase in volume of scans which the Applicant has experienced and projects it will continue to experience once the new equipment is installed and operational, and/or the change in expense for the equipment once the lease is discontinued and the Applicant has purchased its own unit. The Applicant further states both changes will result in greater economic viability of the Applicant's PET operations.
- e. Covered Expenses: The Applicant affirms it will cover all expenses out of its revenue stream and cash reserves. The Applicant states this project will serve only to decrease the Applicant's long-term operational expenses as it eliminates the ongoing lease expenses associated with its mobile PET services. The Applicant further states it can operate with decreased scan volumes from those projected and the Applicant will still be able to continue to operate and be economically viable.

f. Impact of Proposed Project on Health Care Cost: SRHS submits the impact of approving their proposed project will be positive to the health care system in Ocean Springs and the Jackson County area. SRHS states the new equipment will be more efficient, creating better and easier access to service as well as resulting in shorter scan times and higher quality results. SRHS further states this project will eliminate various expenses from the system by replacing what has been a long running lease expense with an investment in equipment that will work better and faster, while costing less on a day-to-day basis.

GR Criterion 5 - Need for the Project

- a. Access by Population Served: The Applicant asserts, as demonstrated by the historical utilization of the mobile and fixed services offered by the Applicant and the provider affidavits, there is a substantial need for the fixed PET services proposed in the population severed by the Applicant, especially the Applicant's Cancer Center patients. The Applicant states it will provide services to and will not discriminate against patients having low incomes, members of a racial or ethnic minority, women, handicapped persons, other underserved groups, or the elderly.
- **b.** Relocation of Services: The Applicant states SRHS is currently providing fixed PET services at its Imaging Center pursuant to an emergency waiver and its proposed project is expected to continue those services. SRHS submits it will provide services to and will not discriminate against patients having low incomes, members of a racial or ethnic minority, women, handicapped persons, or other underserved groups or the elderly.
- c. Current and Projected Utilization of Comparable Facilities: SRHS submits the Applicant is not adding facilities or services to the service area. The Applicant states, while it is fully expected that scan volumes will continue to increase from the current levels, the Applicant is equally confident that it will have no adverse impact on other existing service providers. The Applicant states the proposed project will continue to serve the Applicant's existing patient base. The Applicant further states the application represents a transition from mobile PET services to fixed PET services.
- d. Probable Effect on Existing Facilities in the Area: The Applicant states SRHS is currently providing fixed PET services at its Imaging Center pursuant to an emergency waiver, and this proposed project is expected to continue those services. SRHS submits the Applicant's proposed project does not include additional facilities or services but represents a transition from mobile PET services to fixed PET service.

e. Community Reaction: The application contains nineteen (19) affidavits from physicians and fifteen (15) letters from consumers and government officials in support of the proposed project.

GR Criterion 6 - Access to the Facility or Service

a. Access to Services. The Applicant submits SRHS is accessible to the populations in its service area, including Medicaid recipients, charity/medically indigent patents, racial and ethnic minorities, women, handicapped persons and the elderly. The Applicant further states patients will have access to the proposed service as described in its application.

The following table shows the historical and projected estimated gross patient revenues of health care provided to charity/medically indigent patients for Years 1 and 2 of the proposed project.

	Medically Indigent (%)	Charity Care (%)	Medically Indigent (\$)	Charity Care (\$)
Historical				
Year 2020	5.47	1.45	127,823,231	33,891,823
Historical				
Year 2021	5.77	1.62	164,848,196	46,202,557
Projected				
Year 1	5.77	1.62	169,793,642	47,588,634
Projected				
Year 2	5.77	1.62	174,887,451	49,016,293

Gross Patient Revenue

- **b.** Existing Obligations: The Applicant submits that SRHS does have existing obligations as an IRC Section 501(r) entity, which requires provision of uncompensated care.
- c. Unmet Needs of Medicare/Medicaid and Medically Indigent Patients: The Applicant states it will continue to serve the needs of Medicare, Medicaid and medically indigent patients. The Applicant further states it will not discriminate against any patient based on payor source (or lack thereof for indigent patients).
- **d.** Access to Proposed Facility: The Applicant submits not to discriminate against and to provide free access to the poor, physically handicapped, women, elderly, and members of ethnic and racial minorities to the facility.

e. Access Issues:

- i. Transportation and Travel: The Applicant states patients will have easy access to the Imaging Center as it is centrally located in the heart of the Applicant's service area, less than a mile away from Ocean Springs Hospital. The Applicant asserts patients seeking imaging from the Imaging Center have access to the Patient Transportation Program provided jointly by the Applicant and the Jackson County Board of Supervisors. The Applicant further states transportation is provided in wheelchair accessible buses and vans as demanded on a prescheduled basis and is available to all Jackson County residents. The Applicant included in its application a copy of its Patient Transportation Policies and Procedures.
- ii. **Restrictive Admissions Policy**: The application contains a copy of SRHS' Admissions Policy which ensures access to care by all groups.
- iii. Access to Care by Medically Indigent Patients: SRHS ensures access to care for medically indigent patients through its admissions policies and practices.
- iv. Operational Hours of Service: SRHS states PET services would remain the same as under the current emergency waiver (i.e., Monday through Thursday, 8:00 am to 5:00 pm, with flexibility to provide services on Fridays as needed for patient overflow).

GR Criterion 7 - Information Requirement

The Applicant affirms that SRHS will record and maintain, at a minimum, the information required under this General Review Criterion regarding charity care, care to the medically indigent and Medicaid populations and will make the information available to the Mississippi State Department of Health within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

a. Comparable Services: The Applicant states the target population will continue to have access to PET services at its facility, but with a more efficient and higher quality service.

The Applicant submits PET services are currently provided by two (2) other providers in GHSA 9. Those providers are Merit Health Biloxi in Harrison County and Memorial Hospital at Gulfport also in Harrison County.

The Applicant asserts the primary difference, in the population served between the providers, is the Applicant serves and will serve its own patient base, in particular the patients of its Cancer Center. Therefore, the Applicant proclaims this population is not served by other providers in the service area. The Applicant submits, because SRHS seeks only to serve its patient population, with an emphasis on those within its Cancer Center, there should be no potential for adverse impact to any existing service provider, nor overlap of services.

b. Effect on Existing Health Services

- i. **Complement Existing Services:** The Applicant states the target population will continue to have access to PET services at the facility but with a more efficient and a higher quality service.
- **ii. Provide Alternative or Unique Service:** The Applicant states, due to the effects of the COVID-19 virus, in July 2020 SRHS applied for and receive an emergency waiver to temporarily implement fixed PET equipment and services at the Imaging Center. The Applicant asserts to continue to utilize mobile PET services would limit the capabilities for Cancer Center patients to receive needed scans as quickly as possible.
- iii. **Provide a service for a specified target population:** SRHS states it will continue to service its patient base, in particular its Cancer Center patients.
- iv. Provide services for which there is an unmet need: The Applicant states its desire to have a fixed PET unit is to provide necessary services to its Cancer Center patients, who require timely access to PET services as oncologists rely on PET scans for diagnosis and treatment of patients. The Applicant asserts to continue to utilize mobile PET services would limit the capabilities for Cancer Center patients to receive needed scans as quickly as possible.
- **c.** Adverse Impact. The Applicant submits the primary adverse impact that may result from failure to implement the proposed project would be the accessibility of services for the Applicant's patient base, in particular the Applicant's Cancer Center patients. The Applicant states oncologists rely heavily on PET scans to diagnose and treat patients. The Applicant asserts the proposed project will serve to improve the existing mobile service by improving the quality of images and patient comfort and increasing access to the service by expanding the number of days per week that a patient may receive a PET scan.

d. Transfer/Referral/Affiliation Agreements. SRHS asserts there are no transfer/referral/affiliation agreements between Ocean Springs Imaging Center and other providers in the area because the proposed PET service is provided as part of the Applicant's comprehensive health care system.

GR Criterion 9 - Availability of Resources

- **a.** New Personnel. The Applicant states all personnel currently providing fixed PET services at the Imaging Center under the emergency waiver will continue in their positions; therefore, no new personnel are required.
- **b. Contractual Services.** The Applicant states this criterion is not applicable to the proposed project.
- c. Existing Facilities or Services. The Applicant states it currently has the personnel needed to staff the proposed project; therefore, no new personnel are needed.
- d. Alternative Uses of Resources. The Applicant states it considered the continual leasing of mobile PET equipment to provide services; however, the improved scan quality of a fixed PET scanner and the increased accessibility to scans for its Cancer Center patients far outweighed any alternative uses of existing resources available to the Applicant.

GR Criterion 10 – Relationship to Ancillary or Support Services

- a. Support and Ancillary Services. The Applicant asserts a full complement of diagnostic imaging services is available within the Health System with most located at the Imaging Center. The Applicant affirms that all necessary support and ancillary services for the proposed project are available.
- **b.** Changes in Costs or Charges. The Applicant states SRHS does not project any change in costs or charges as a result of the proposed project.
- c. Accommodation of Changes in Cost or Charges. The applicant submits this criterion is not applicable.

GR Criterion 11 – Health Professional Training Programs

The Applicant states SRHS does not anticipate the service will be used for training purposes.

GR Criterion 12 – Access by Health Professional Schools

The Applicant states this criterion is not applicable.

GR Criterion 13 – Access by Individuals Outside Service Area

The Applicant affirms this criterion is not applicable.

GR Criterion 14 - Construction Projects

The Applicant affirms this project does not involve new construction; however, the Applicant did renovate existing space in its Imaging Center.

GR Criterion 15 – Competing Applications

There are no competing applications on file with the Mississippi State Department of Health for the acquisition of fixed PET equipment or the offering of fixed PET services.

GR Criterion 16 - Quality of Care

- **a. Past Quality of Care.** The Applicant submits SRHS is committed to the provision of prompt, efficient, high-quality service to all patients who present for PET procedures. The Applicant states, since its inception, SRHS has taken all needed actions to meet this commitment and the quality of its service has never been questioned.
- **b.** Improvement of Quality of Care. The Applicant states the project will improve the quality of care being delivered to the Applicant's growing patient base by increasing the efficiency with which the Applicant is able to offer its services and will result in improved scan quality over the mobile equipment used at its hospital locations. The Applicant further states this will enable patients to receive a higher quality product more efficiently and with greater value.
- **c.** Accreditations and/or Certifications. The Applicant's Cancer Center is accredited by the Commission on Cancer, a program of the American College of Surgeons.

IV. FINANCIAL FEASIBILITY

A. <u>Capital Expenditure Summary</u>

The total estimated capital expenditure is allocated as follows.

	ltem	Cost (\$)	Percent (%) Of Total	
a.	Land Cost	\$ 0	0%	
b.	Site Preparation	0 0%		
C.	Other	0	0%	
d.	New Construction	0	0%	
e.	Renovation	325,620	12.3	
f.	Capital Improvements	0	0%	
g.	Fees (architectural, consultant, etc.)	30,000	1.1	
h.	Contingency Reserve	60,000	2.3	
i	Capitalized Interest	0	0%	
j	Other	0	0%	
k.	Fixed Equipment	2,239,500	84.3	
١.	Non-Fixed Equipment	0	0%	
	Total Proposed Capital			
	Expenditure	<u>\$2,655,120</u>	<u>100.00%</u>	

B. <u>Method of Financing</u>

The Applicant states the proposed project will be financed by SRHS through cash reserves.

C. Effect on Operating Cost

The Hospital's three-year projected operating statement is presented at Attachment 1.

D. Cost to Medicaid/Medicare

The applicant projects the gross patient revenue cost to third party payors as follows:

Payor Mix	Utilization Percentage (%)	First Year Revenue (\$)		
Medicare	64.00 %	6,826,820.00		
Medicaid	6.00%	600,538.00		
Commercial	20.00%	2,164,044.00		
Self Pay	1.00%	157,198.00		
Charity Care	0.00%	0.00		
Other	8.00%	883,864.00		
Total	100.00%	\$10,632,464.00		

*Total may differ due to rounding.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. In a letter dated March 29, 2022, the Division of Medicaid indicated the Division had no comment.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the acquisition of fixed PET equipment and the implementation of PET services contained in the FY 2022 *Mississippi State Health Plan, Second Edition* and the *Mississippi Certificate of Need Review Manual, September 1, 2019, Revision*; and the duly adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Singing River Health System – Ocean Springs Imaging Center for the Acquisition of Fixed PET Equipment and the Implementation of PET Services at an Outpatient Imaging Center.

Attachment 1

Singing River Health System - Ocean Springs Imaging Center Three-Year Operating Statement (Project Only)							
	•	Year I		Year 2		Year 3	
Devenue	_						
Revenue Patient Revenue:							
	\$	78,014.00	\$	80,354.00	\$	82,765.00	
Inpatient Outpatient	Ŧ	,632,464.00		10,951,438.00	Ŧ	1,279,981.00	
Gross Patient Revenue		,710,478.00		11,031,792.00		1,362,746.00	
Gloss Fallent Revenue	10	,710,478.00		11,031,792.00		1,302,740.00	
Charity Care		189,575.00		195,263.00		201,121.00	
Deductions from Revenue	9	,156,032.00		9,430,713.00		9,713,634.00	
Net Patient Revenue		,364,871.00	\$	1,405,817.00	\$	1,447,991.00	
		0.00		0.00			
Other Operating Revenue		0.00		0.00	•	0.00	
Total Operating Revenue	\$1	,364,871.00	\$	1,405,817.00	\$	1,447,991.00	
Expenses							
Operating Expenses:		407.050.00	۴	100.000.00	¢	404 704 00	
Salaries	\$	127,056.00	\$	130,868.00	\$	134,794.00	
Benefits		21,935.00		22,593.00		23,271.00	
Supplies		183,291.00		188,790.00		194,453.00	
Services		0.00 348,595.00		0.00 29,050.00		0.00	
Lease		0.00		429,624.00		0.00	
Depreciation Interest		0.00		429,624.00		468,681.00 0.00	
Other		35,409.00		36,471.00		37,565.00	
Total Operating Expense	¢	716,286.00	\$			858,764.00	
	Ŷ	710,200.00	4	5 057,590.00	,	\$ 030,704.00	
Net Operating Income (Loss)	\$	648,585.00	\$	568,421.00		\$ 589,227.00	
Assumptions							
Inpatient days		0		0		0	
Outpatient days		0		0		0	
Procedures		1,440		1,483		1,528	
Charge/outpatient day		N/A		N/A		N/A	
Charge per inpatient day		N/A		N/A		N/A	
Charge per procedure	\$	7,438.00	\$	7,438.00	9		
Cost per inpatient day	Ť	N/A	Ψ	N/A	,	N/A	
Cost per outpatient day		NA		NA		NA	
Cost per procedure	\$	497.00	\$	565.00	\$	562.00	

*Total may differ due to rounding.